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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FLOOD, MICHELE C	
ART UNIT	PAPER NUMBER
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/088,851	MSIKA ET AL.	
	Examiner	Art Unit	
	Michele Flood	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *61,62,70-72,77,82,84,85 and 88-92* is/are pending in the application.

4a) Of the above claim(s) *88-90 and 92* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *61,62,70-72,77,82,85 and 91* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

Applicant's election with traverse of Group I, Claims 61, 62, 70-72, 77, 78, 78, 82, 84 and 91, as well as the species of Group A: unsaponifiable materials from sunflower oil readable on Claims 61, 62, 70-72, 76, 82, 84 and 91, and the species of Group B: atopic dermatitis readable on Claims 61, 62, 70-72, 76, 82, 84 and 91, in the reply filed on December 15, 2008 is acknowledged. The traversal is on the ground(s) that a search of for the "invention" of Group I will necessarily require consideration of the subject matter of the "invention" of Group II. Applicant's arguments have been fully considered, but are not fully persuasive with regard to the restriction between the two groups for all of the reasons set forth clearly in the previous Office action. However, the requirement for election of species is hereby withdrawn, as Applicant's arguments have been found persuasive.

The requirement is still deemed proper and is therefore made FINAL.

Claims 61, 62, 70-72, 77, 78, 78, 82, 84, 85 and 91 are under examination.

Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 61, 62, 70-72, 77, 78, 78, 82, 84, 85 and 91, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly applied as necessitated by amendment.

The metes and bounds of Claim 61, lines 9-10, are rendered vague and indefinite by the phrase, "said skin lipids are selected from the group consisting of cholesterol, cholesterol sulfate, ceramide, and ceramide 2", because it is unclear as to whether the phrase refers to the skin lipids "of a subject having a quantity of skin lipids" or to skin lipids that increase after the administration of the claim-designated ingredients. The lack of clarity renders the claim ambiguous.

The metes and bounds of Claim 91, lines 7-10, are rendered vague and indefinite by the phrase, "said skin lipids are selected from the group consisting of cholesterol, cholesterol sulfate, and ceramides", because it is unclear as to whether the phrase refers to the skin lipids "of a subject having a quantity of skin lipids" or to skin lipids that increase after the administration of the claim-designated ingredients. The lack of clarity renders the claim ambiguous.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Objections

Claim 61 is objected to because of the following informalities: Claim 61, line 15, recites the abbreviation "UV". Abbreviations in the first instance of claims

should be expanded upon with the abbreviation indicated in parentheses. Applicant may overcome the rejection by replacing "UV" in line 15 of Claim 61 with Ultraviolet (UV). The abbreviations can be used thereafter.

. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a

later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 61, 62, 70-72, 77, 78, 78, 82, 84, 85 and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sekimoto (JP 57131716 A) in view of Milkova et al. (Milkova T et al. Nahrung (1977); 21(1): 1-6. Study on the chemical nature of sterols contained in Bulgarian sunflower oil.), Alonso et al. (Alonso L et al. Journal of the American Oil Chemists' Society (1997); 74(2): 131-135. Determination of mixtures in vegetable oils and milk by fat analysis of sterol fraction by gas chromatography.) and Brun et al. (N) . Newly applied as necessitated by amendment.

Applicant claims a method of treating a skin condition having a quantity of skin lipids comprising administering an effective amount of a composition comprising at least one plant oil product selected from the group consisting of oil distillate of sunflower oil and unsaponifiable materials from sunflower oil; wherein said quantity of skin lipids increases after administration of the composition, said skin lipids are selected from the group consisting of cholesterol, cholesterol sulfate, ceramide 1, and ceramide 2; and wherein the skin condition is sensitive skin, dry skin, pruritus, ichtyosis, acne, xerosis, atopic dermatitis, cutaneous desquamation, skin subjected to actinic radiation or skin subjected to ultraviolet (UV) radiation. Applicant further claims the method of claim 61 wherein the subject has an epidermal skin barrier and the skin lipids are lipids of the epidermal skin barrier; wherein the plant oil product is present in an amount of

between about 0.01% and 100% by weight relative to the total weight of the composition; wherein the composition is administered topically, orally, enterally or parenterally; wherein the composition is applied to the skin, the neighboring mucous membranes and/or the integuments; and, wherein the composition is administered to treat skin that is sensitive, irritated or reactive. Applicant further claims the method of claim 71, wherein said unsaponifiable materials are present in said plant oil product in an amount of 10 to 20% by weight. Applicant further claims the method of claim 84, wherein the composition is a cosmetic, pharmaceutical or dermatological composition; wherein the cosmetic, pharmaceutical or dermatological composition comprises an oil solution, a water-in-oil emulsion, an oil-in-water emulsion, a micro-emulsion, an oily gel, an anhydrous gel or a dispersion of vesicles, microcapsules or microparticles.

Applicant claims a method of treating a skin condition having a quantity of skin lipids comprising administering an effective amount of a composition comprising at least one plant oil product selected from the group consisting of oil distillate of sunflower oil and unsaponifiable materials from sunflower oil; wherein said quantity of skin lipids increases after administration of the composition, said skin lipids are selected from the group consisting of cholesterol, cholesterol sulfate, and ceramides; and wherein the skin condition is sensitive skin, dry skin, pruritus, ichtyosis, acne, xerosis, atopic dermatitis, cutaneous desquamation, skin subjected to actinic radiation or skin subjected to ultraviolet (UV) radiation.

Sekimoto teaches a method of administering an effective amount of a composition comprising sitosterol obtained from various vegetable oils (e.g.

soybean oil, etc.), for the treatment of dry skin and keratinization and softening of skin. The composition taught by Sekimoto comprises 0.3% sitosterol or 2.0% of sitosterol-containing vegetable oils. Sekimoto further teaches that the method of administering the referenced composition increases the level of skin lipids in treated patients. Sekimoto further teaches that administration of unsaponifiable materials from the oils. Sekimoto further teaches, "GLC analysis of the fluid secreted from the sole of a foot showed that it contained cholesterol, sitosterol and triterpene alcohols. The content of sitosterol in the secreted fluid is higher than that in blood. Sitosterol was found to exhibit an effect against drying of the surface of foot-sole and keratinisation of the skin."

The teachings of Sekimoto are set forth above. Sekimoto teaches the instantly claimed invention except for administering an effective amount of a composition comprising at least one plant oil product selected from the group consisting of oil distillate of sunflower oil and unsaponifiable materials from sunflower oil. However, it would have been obvious to one of ordinary skill in the art to add either of the instantly claimed ingredients to the method composition taught by Sekimoto or to replace the method composition taught by Sekimoto with either of the claim-designated ingredients to provide the claimed method of treating a skin condition because at the time the invention was made Milkova taught that the major sterols of sterol fractions of crude sunflower oil, as well as those of the technical lecithin, the pitch and the deodorizer distillate of the latter oil, are sitosterol, campesterol and stigmasterol; Alonso also taught that unsaponifiable materials from sunflower oil comprise sitosterol, campesterol and

stigmasterol; and, moreover, Brun taught a composition comprising a mixture of jojoba oil and sunflower oil and at least one unsaponifiable of jojoba oil, by weight from 20-45%, and/or at least one unsaponifiable of sunflower oil, by weight from 25-40%, that was useful in the making of cosmetics having lubricating properties and leaving a hydrophobic film on the surface of the skin to improve or maintain the suppleness of skin by preventing water evaporation from the skin. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add either of the claim-designated ingredients to the method composition taught by Sekimoto or to replace the method composition taught by Sekimoto with either of the claim-designated ingredients to provide the claimed method of treating a skin condition because like Alonso, Milkova taught that distillate of sunflower oil and unsaponifiable materials from sunflower oil comprise the same or essentially the same sterol fractions contained in the unsaponifiable sterol fraction of vegetable oils comprising sitosterol taught by Sekimoto having the beneficial functional effect of increasing skin lipids in persons having dry skin or keratinized skin conditions; and Brun suggested that compositions comprising unsaponifiable materials from sunflower oil, like the unsaponifiable materials contained in the composition taught by Sekimoto, were useful in methods of treating dry senile, dry or rough skin on page 1, lines71-75. Thus, given the references before him or her, the instantly claimed method of treatment would have been no more than a matter of routine optimization to provide a result effect variable for either the addition or replacement of one functional equivalent for the other wherein it

would be highly reasonable to assume that compositions comprising the same or essentially the same ingredients would provide the same beneficial functional effect for treating skin that is dry, sensitive, irritated or reactive and increasing skin lipids.

As the teachings of the references indicate that the various proportions and amounts of the ingredients used in the claim-designated composition(s) for the claimed method of treating skin condition are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele Flood
Primary Examiner
Art Unit 1655

MCF
March 39, 2009

/Michele Flood/
Primary Examiner, Art Unit 1655